

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Standard Instruments Versus Microdebrider in Endoscopic Sinus Surgery- An Outcome Based Comparative Study: A Tertiary Care Hospital Experience

Protocol summary

Study aim

To compare the outcome after using standard instruments versus microdebrider in endoscopic sinus surgery in the patients of chronic rhinosinusitis with polyposis

Design

A concealed randomized single blinded parallel clinical trial (interventional study) for 130 subjects from 2024 to 2025 which will be followed for 6 months to assess outcome.

Settings and conduct

Trial will be conducted in outpatient and operation theatre departments of Otorhinolaryngology of Bahawalpur Victoria Hospital Bahawalpur Pakistan with randomization of participants by lottery method keeping the participants blinded for groups.

Participants/Inclusion and exclusion criteria

All patients from 15 to 65 years of age of both the gender having chronic Rhinosinusitis with nasal polyposis requiring endoscopic sinus surgery will be included in the study. Those patients having recurrent disease, history of previous surgery and with nasal septal deviations will be excluded from the study

Intervention groups

Group A patients will receive one modality of intervention (microdebrider) while group B patients will receive other modality of intervention (standard instruments) during endoscopic sinus surgery

Main outcome variables

Intraoperative bleeding, disease recurrence and synechia formation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240825062865N1**

Registration date: **2024-09-22, 1403/07/01**

Registration timing: **prospective**

Last update: **2024-09-22, 1403/07/01**

Update count: **0**

Registration date

2024-09-22, 1403/07/01

Registrant information

Name

Asim Shafique

Name of organization / entity

Quaid e Azam medical college Bahawalpur

Country

Pakistan

Phone

+92 300 9687395

Email address

drasimkmc@qamc.edu.pk

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-12-01, 1403/09/11

Expected recruitment end date

2025-12-01, 1404/09/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Standard Instruments Versus Microdebrider in Endoscopic Sinus Surgery-An Outcome Based

Public title

Use of microdebrider in endoscopic sinus surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Chronic Rhinosinusitis with nasal polyposis requiring endoscopic sinus surgery

Exclusion criteria:

Recurrent disease with history of previous surgery
Sinonasal tumours
Chronic Rhinosinusitis along with Deviated nasal septum necessitating septal surgery
Concomitant Heart disease, Diabetes Mellitus and Hepatorenal disease
Patients on regular antiplatelet drugs

Age

From **15 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **130**

Randomization (investigator's opinion)

Randomized

Randomization description

Lottery method will be used to divide the patients, and all selected subjects will be asked to choose and pick a slip from all mixed up slips whereas half-slips will be containing letter 'A' and other half will contain letter 'B' and then the particular case will be placed in that respective group accordingly. All patients in Group A will undergo ESS (Endoscopic polypectomy, endoscopic stripping of diseased sinuses mucosa with removal of disease and sinus lavage, Endoscopic middle meatus antrostomies) using microdebrider while in group B patients undergo ESS with conventional routine instruments. The description of specific use of instruments with respect to group A and B will be concealed from the participants.

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be asked to pick a slip from a box containing equal mixed slips of letter A and B. Participants will be blinded regarding type of intervention for both A and B groups adopted.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical review committee, Department of medical education QAMC

Street address

Circular road

City

Bahawalpur

Postal code

63100

Approval date

2023-08-21, 1402/05/30

Ethics committee reference number

2245

Health conditions studied

1

Description of health condition studied

Endoscopic sinus surgery for Chronic Rhinosinusitis with polyposis

ICD-10 code

J32.9

ICD-10 code description

Rhinosinusitis, Endoscopic sinus surgery. Microdebrider

Primary outcomes

1

Description

Intraoperative blood loss

Timepoint

2 hours

Method of measurement

Measurement of suction bottles and weight of soaked guaze pieces

Secondary outcomes

1

Description

Nasal synchiaie

Timepoint

2 months

Method of measurement

Nasoendoscopy

2

Description

Disease recurrence

Timepoint

6 months

Method of measurement

Nasoendoscopy and computed tomography

Intervention groups

1

Description

The participants who will undergo surgical treatment with microdebrider will be labelled as intervention group while those who will undergo surgical treatment with standard conventional instruments will be labelled as comparison group.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Out patient Department of Bahawalpur Victoria Hospital Bahawalpur Punjab

Full name of responsible person

Areej sajid

Street address

ENT Department BVH. Circular road

City

Bahawalpur

Postal code

63100

Phone

+92 337 7506123

Email

Dr.merryshah@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bahawalpur Victoria Hospital Bahawalpur

Full name of responsible person

Muhammad Asim Shafique

Street address

ENT dept. BVH

City

Bahawalpur

Postal code

63100

Phone

+92 300 9687395

Email

drasimkemc@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Bahawalpur Victoria Hospital Bahawalpur

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Quaid e Azam medical college

Full name of responsible person

Muhammad Asim Shafique

Position

Consultant

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

ENT Department BVH, Circular road

City

Bahawalpur

Province

Punjab

Postal code

63100

Phone

+92 300 9687395

Email

drasimkemc@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Quaid e Azam medical college

Full name of responsible person

Ansar Javed

Position

Post graduate resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

ENT Department, BVH, Circular road

City

Bahawalpur

Province

Punjab

Postal code

63100

Phone

+92 342 7229607

Email

ansarbhatti57@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Quaid e Azam medical college

Full name of responsible person

Areej sajid

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Ear, Nose, and Throat

Street address

ENT department, BVH, Circular road

City

Bahawalpur

Province

Punjab

Postal code

63100

Phone

+92 337 7506123

Email

Dr.merryshah@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data will be collected on a predestined proforma/ question are for every patient that can be made available for sharing.

When the data will become available and for how long

When all the data of all participants is completed and analysed. It will take the time duration when the complete follow up period is over.

To whom data/document is available

For all the investigators and colleagues working in the institution and may be shared to other institutional colleagues on request after the approval.

Under which criteria data/document could be used

Requests of data sharing and availability will be analysed and considered by the team of authors/investigators and in case the matter is agreed, it will be forwarded to the department of institutional review board/ ethical committee for final approval.

From where data/document is obtainable

The registrar of the relevant department of institution through postal address. Bahawalpur Victoria Hospital circular road, Bahawalpur Pakistan, dr.shahzadbwp@gmail.com

What processes are involved for a request to access data/document

After the arrival of requests, these will be put up for consideration before the team of investigators and if accepted, will be forwarded to ethical board of institutions for final approval

Comments